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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,243	12/21/2000	Narendra Parikh	JBP514	8350

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EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
07/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/745,243	PARIKH ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8,9,11,13,14,16-19,21,22,24,31-33,35,36 and 73-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8,9,11,13,14,16-19,21,22,24,31-33,35,36 and 73-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/12/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Andriae M. Holt.

This Office Action is in response to Applicant's amendments filed June 9, 2008. Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 are pending in the application. Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 will presently be examined to the extent they read on the elected subject matter of record.

Information Disclosure Statement

The Information Disclosure Statement filed August 12, 2008 is acknowledged.

Status of the Claims

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

The rejection of claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 under 35 U.S.C. 103(a) as being unpatentable over Maruyama et al. (US Pat. 5,789,014) in view of Zingerman et al. (US Pat. 3,431,138), Friend et al. (US Pat. 6,139,865), CA 2068366 and Norling et al. (US Pat. 5,958,458) **is maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maruyama et al. (US Pat. 5,789,014) in view of Zingerman et al. (US Pat. 3,431,138), Friend et al. (US Pat. 6,139,865), CA 2068366 and Norling et al. (US Pat. 5,958,458).

Maruyama et al. disclose that a solid preparation with a coating is used fro enteric properties, controlled release, masking bitter tastes, etc. (Column 1, lines 20-23). It is disclosed that the first coating can contain a combination of polymers, such as cellulose acetate phthalate and ethyl cellulose (column 5, lines 35-63). It is disclosed that the solid preparation can be further coated with a granule adhesion preventing agent, including mixtures of agents such as aqueous polymers, such as hydroxypropylmethyl cellulose and polyethylene glycol (Column 6, lines 20-28).

Zingerman et al. discloses that addition of polyethylene glycol to a cellulosic coating composition improves the flexibility and smoothness of the finished coating layer (Column 2, lines 38-43).

Friend et al. disclose the use of ethyl cellulose, cellulose acetate phthalate and/or hydroxypropylmethyl cellulose phthalate and the like for effective taste masking of drugs (Column 7, lines 22-39). It is taught that the microcapsules provide dissolution of at least about 90% at 45 minutes (Column 8, lines 36-66). It is taught that the particle size

of the microcapsules will be in the range of a few microns up to about 1000 microns or more, with particle sizes in the approximately 30 microns to 800 microns, and the particles sizes in the range of approximately 40 microns to 250 microns particularly preferred and that those skilled in the are will recognize that the components of the microcapsules, the relative quantities of the drug and polymeric coating material, the size of the microcapsules and other parameters, can be easily varied to provide of different degrees of taste masking and various release profiles (Column 8, lines 31-43).

CA 2068366 disclose that ethyl cellulose is a water-insoluble polymer and that cellulose acetate phthalate and hydroxypropylmethyl cellulose phthalate are enteric polymers (Pg. 8, lines 26-33, Pg. 9, lines 30-38).

Norling et al. discloses a particle having two or more layers of coating, including film coatings and modified release coatings where the coating provides desired release profile of the active substance or masks the bad-tasting active substances (Column 8, lines 36-68, Column 9, Column 10, lines 1-34).

The prior art discloses a solid preparation containing a first coat containing a mixture of ethyl cellulose and cellulose acetate phthalate and a second coat containing a mixture of HPMC and PEG. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose using the ratio of HPMC to PEG of about 80:20 to about 20:80. However, the prior art amply suggests the same as the prior art discloses the combination of the same and that polyethylene glycol added to a cellulosic coating composition improves the flexibility and smoothness of the finished coating. As such, it would have been well within the skill of one of ordinary skill

in the art to combine various amounts as desired to provide a desired smoothness of the second coating layer.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Response to Arguments

Applicant's arguments filed June 9, 2008 have been fully considered but they are not persuasive. Applicant argues that Maruyama fails to disclose a second coating containing a mixture of HPMC and PEG at a ratio of 80:20 to about 20:80. Applicant also argues that Maruyama fails to specifically disclose or suggest the use of a coating comprised only of “aqueous polymers”. Applicant argues that the prior art fails to teach the combination of the second layer comprised of anti-grit and film-forming polymers. In response to applicant’s arguments, Maruyama does teach that the second coating can be mixtures of agents such as aqueous polymers, such as hydroxypropylmethyl cellulose and polyethylene glycol (see col. 6, lines 23-27). It would have been obvious to one skilled in the art at the time the invention was made that a combination of the polymers, hydroxypropylmethyl cellulose and polyethylene glycol, could be used as the second coating because the list of possible agents to use as the second coating is fairly limited. Therefore, it would have been obvious to the skilled artisan to try any number of the combinations of polymers to get the desired results. In reference to applicant’s arguments that Maruyama does not disclose or suggest the use of a coating comprised

only of “aqueous polymers”, Maruyama does teach and suggest that the combinations can be made by the inclusion of the "aqueous polymers" among the list of desired agents to use as polymers for the second coating (see col. 6, lines 23-27)In addition, the anti-grit polymers and film-forming polymers claimed in the instant application, are the same compounds, polyethylene glycol (anti-grit) and hydroxypropylmethyl cellulose (film forming polymer), claimed in the prior art, therefore, the use of the components would have been obvious, as the terms are synonymous .

In reference to the ratio of HPMC to PEG of 80:20 to about 20:80, absent data showing unexpected results, as noted in the previous office action, the use of the ratio would be a matter of routine experimentation and optimization. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Applicant argues that Maruyama fails to disclose or suggest oral dosage forms of chewable tablets and rapidly dissolving tablets. In response to applicant’s arguments, while Maruyama does not disclose or suggest the new limitation that the composition is a chewable tablet or rapidly dissolving tablet, when combined with the prior art cited, these formulations are obvious. Specifically, Friend teaches the term “pharmaceutical formulation” containing the microcapsules in combination with carriers or excipients suited to a selected drug delivery platform, such as effervescent formulation, a chewable tablet, or a fast melting formulation (col. 4, lines 56-61). Friend teaches a core, a first polymeric coating that can be ethyl cellulose, cellulose acetate phthalate and/or hydroxypropylmethyl cellulose phthalate and the like for effective taste masking

of drugs, and a second polymeric coating. Norling teaches formulations include granules, chewable tablets, and lozenges (col. 13, lines 29-36). Norling teaches the use of excipients in the formulations, including sucrose, sorbitol, mannitol, lactose and starches (water soluble compressible carbohydrates, excipients) (col. 13, lines 40-46). It would have been obvious to the skilled artisan that excipients and additives that are well known in the art, such as mannitiol, lactose, starch and the like could be added to the formulations as taught by Maruyama to make chewable tablets or rapidly dissolving tablets, see Friend col. 9, lines 56-66. Maruyama also teaches in the preparation of tablets the use of spray dried lactose and corn starch to aid in the formulation of tablets (col. 7, lines 35-47).

Applicant argues the prior art fails to teach how the coating performs as a texture masking agent and that prior art teaches taste masking agents. In response to applicant's argument that the composition is a texture masking agent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Friend teaches the microcapsules and effervescent tablets were evaluated for flow, color, mouthfeel/grittiness (texture masking), taste masking, bitterness, aftertaste, and overall acceptance. Therefore, it would have been obvious to the skilled artisan in evaluating taste of a composition, the texture and mouthfeel would also be evaluated. Also, that the combinations of the same components would provide good mouthfeel, as well as, taste masking.

The claims remain rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
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/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616